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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

7590 04/10/2008  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
One Maritime Plaza  
San Francisco, CA 94111

EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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04/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/966,036	<b>Applicant(s)</b> HAPP, DORRIE M.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive in view of the amendment and, therefore, the finality of that action is withdrawn.

Examiner acknowledges receipt amendment and remarks filed 3/31/08. Claim 4 is amended. Claims 2, 7, 10, 14, 15, 17, 19, 21, 23, 27, 28, 34, 39-46, 50 and 52 are canceled. Claim 4 is pending.

### ***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn.**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is new matter.

4. Claim 4 recites that the mass ratio of the light and/or UV protective compound to the polymer in the second layer is between about 3:1 and about 1:3. This limitation was first introduced in canceled claim 5 in the amendment of 09/10/2004. The specification as filed does not envision that the structure of the coated stent to be one in which the ratio of the light and/or UV protective compound to the polymer in the second layer be between about 3:1 and about 1:3. The specification at paragraph [0053], published application, refers to layer 6 in which "the ratio, by mass, of the light- and/or UV-radiation protective compound to the polymer is between about 3 to 1 (at the lower range of concentrations of the solution to be sprayed) and about 1 to 3 (at the higher range)." But layer 6 in Figure 2B is the 3rd layer and not the second layer. Applicant may overcome this rejection by removing the new matter from the claim of specifically point to section(s) of the specification that provides support for that structure and limitation.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites "between about ...." But between about comprises a range that is between 3:1 and 1:3 and another range that is covered by the about that begins at slightly less than 3 or slightly greater than 3. Thus, the boundaries of protection sought by the claim is not clear in view of the two ranges recited in one supposed range, thus making the claim indefinite. Correction is respectfully requested --- applicant may use about in place of the "between about."

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 2001/0014717, submitted by applicant on form 1449).

Hossainy discloses prosthetic device such as a stent or self expandable stent, which is coated with a polymer drug composition (paragraphs [0014], [0015]); the drug polymer is coated over by another layer of polymer (paragraph [0070]); the polymer in both layers, the polymer drug layer and polymer barrier layer could comprise the same polymers and (paragraph [0070]); in one embodiment, the particles such as inorganic particles of activated charcoal or titanium nitride (paragraphs [0071]-[0073]) are included in the blend. Hossainy contemplates the use of a number of drugs for delivery with the coated stent (paragraph [0062]) and specifically mentions anti-neoplastic drugs such as paclitaxel and docetaxel (paragraph [0062]). Hossainy does not say that paclitaxel is light sensitive but it is known that paclitaxel is as evidenced by instant claim 4. Hossainy teaches the coated stent of the instant claim except that Hossainy does not teach the amount of the particles and the polymer or the ratio of the particles to the polymer. However, taking the teaching of Hossainy, one having ordinary skill in the art at the time the invention was made has good reason to use amounts of the particles and polymer in ratios that would produce the desired coating composition and the desired coated stent for expected delivery of active agents upon implantation. Furthermore, there is no demonstration in

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applicant's specification showing that certain amount of the light or UV-protective compound relative to certain amount of the polymer in the top-coating composition (recited ratios) provides unusual results to the coated medical device. For example, the specification at paragraph [0053] of the published application, states "the ratio, by mass, of the light- and/or UV-radiation protective compound to the polymer is between about 3 to 1 (at the lower range of concentrations of the solution to be sprayed) and about 1 to 3 (at the higher range)" without further description of what if any unexpected/unusual results from the cited ratio provides to the device. In the absence of factual evidence the ratio of the UV-protective agent to the polymer is not inventive over the prior art that is silent of the ratio.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tuch (us 5,624,411) or Zhong (US 6,179,817) in view of over Kanikanti et al. (US 5,900,425) and further in view of Sinclair et al. (US 5,760,118).

Tuch discloses multiply coated stent, with the coating composition containing polymer and active agent such as vincristine (column 2, lines 31-67; column 3, lines 8-38; column 6, line 18).

Zhong discloses multicoated stent with the coating composition containing polymer and active agent such as paclitaxel, docetaxel (column 10, line 61; column 13, lines 7-15; column 9, line 34; column 5, lines 59-66; column 6, lines 12-61).

9. Neither Tuch nor Zhong teaches the use of carbon black or titanium nitride oxide with the coating compositions containing the active agents. However, it is known in the art to use metal particles such as titanium dioxide and iron oxide as protective compounds to protect light

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sensitive active agents according to Kanikanti (column 4, lines 7-14; column 2, lines 23-25, 52-67; column 3, lines 26-46; column 4, lines 6-14). Furthermore, Sinclair teaches that carbon black, zinc oxide and substituted benzophenones are UV-light absorbers which when added to a composition make the composition more resistant to degradation by ultraviolet radiation (column 31, line 67 to column 32, line 4).

Therefore, taking the teachings of the references together, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that including carbon black or iron oxide would protect the active agents from light degradation. Regarding the ratio of the light or UV protecting compound, it is noted that there is no demonstration in applicant's specification showing that certain amount of the light or UV-protective compound relative to certain amount of the polymer in the top-coating composition (recited ratios) provides unusual results to the coated medical device. For example, the specification at paragraph [0053] of the published application, states "the ratio, by mass, of the light- and/or UV-radiation protective compound to the polymer is between about 3 to 1 (at the lower range of concentrations of the solution to be sprayed) and about 1 to 3 (at the higher range)" without further description of what if any unexpected/unusual results from the cited ratio provides to the device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Examiner, Art Unit 1618